UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,626	08/30/2001	Norman G. Anderson	42159	6779

7590 11/05/2003

John C, Robbins
Large Scale Biology Corporation
3333 Vaca Valley Parkway
suite 1000
Vacaville, CA 95688

EXAMINER	
MARSCHEL, ARDIN H	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,626	ANDERSON ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *15,17-58 and 60-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) [illegible] (1 sheet)
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1-14, 16, and 59), filed 10/13/03, is acknowledged. The traversal is on the ground(s) that the instant application would be viewed as one unified invention rather than a collection of 11 Groups, due to its filing before a recent anthrax attack. This is not found persuasive because the occurrence or not of an anthrax attack is not the basis for the distinctness between said 11 Groups. This argument is non-persuasive therefore due to not being directed to the basis for the restriction requirement as set forth in the previous office action, mailed 9/11/03, which is still deemed proper. Applicants further argue that the antibody, its preparation and usage should constitute the same search regardless of the classification and comparable issues. In response, again as above, applicants have not argued or negated the basis for the distinctness of these Groups and therefore the traversal argument is not directed to the basis for the restriction requirement which is therefore also deemed still proper.

The requirement is still deemed proper and is therefore made FINAL.

VAGUENESS AND INDEFINITENESS

Claims 1-14, 16, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, last line, cites the derivation of sequences from "plural nucleic acids". This phrase lacks clear antecedent basis because it lacks wording which defines whether said "plural nucleic acids" are the extracted nucleic acids which are sequenced

in the extracting and sequencing steps or whether other plural nucleic acids from, for example, a collection of various infectious particles are meant for comparison in order to identify the infectious particle in the sample cited earlier in claim 1. It may be implied that the nucleic acids in the extracting and sequencing are the plural nucleic acids in the last line of claim 1, but this is an assumption and not clearly and conciserly set forth as required in 35 U.S.C. 112, second paragraph. Claims dependent directly or indirectly from claim 1 are also rejected hereinunder due to their dependence. Clarification via clearer claim wording is requested.

In claim 1, line 5, the word "complementary" is cited which causes the claim to be vague and indefinite as to what is meant. Several interpretations are possible as follows for said word. One is the well known interpretation that complementarity may not be exact over a whole sequence. Complementary nucleic acids commonly include complementarity less than 100% such as 90%, or less, complementarity for hybridization probing. Secondly, and closely related, is that sequencing procedures are known which sequence inserted nucleic acids wherein the insertion is in a clone for sequencing methods where the clone vector or plasmid may not be complementary to the insert which is desired to be sequenced. Consideration of the presumed sequencing usage of the complementary sequence in lines 5-6 of instant claim 1 may imply that only exactly complementarity is meant. This, however, is an presumption or assumption and not clearly and concisely worded as required under 35 U.S.C. 112, second paragraph. Claims dependent directly or indirectly from claim 1 are also

rejected hereinunder due to their dependence. Clarification via clearer claim wording is requested.

SCOPE OF ENABLEMENT REJECTION

Claims 1, 2, 7-12, 14, 16, and 59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determination of the identity of an infectious particle via comparing the sequence thereof to a database of known sequences as in instant claim 3, does not reasonably provide enablement for any generic identity determination. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

The identification of an infectious particle is only reasonably performable or predictable via some type of comparison with known particle sequences so as to determine if the sample's content of infectious particle(s) is an already known type or a new type that has not yet been identified previously. None of this identification practice is reasonably predictably doable without using said comparison as in instant claim 3, for example. Thus, undue experimentation is required for claim embodiments which are not limited as in instant claim 3, for example.

PRIOR ART REJECTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 9, 10, 12, 13, and 59 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Reyes et al. (P/N 5,218,099).

Reyes et al. purifies virus particles (infectious particles as instantly claimed) as summarized in the abstract. Cloned genetic material is then cited as useful for identifying virus particles in said abstract. The purification of virus particles with the extraction of nucleic acids is further detailed in column 2, lines 38-68, including buoyant density values (from centrifugation as in instant claim 9 also well known as performed

with containment as in instant claim 59) as in instant claim 10. The bridging sentence between columns 2 and 3 disclose sequence transcription and cDNA sequences (as in instant claim 12) of said viral particles. Sequencing specifically is determined or identified as in column 3, lines 45-55. These disclosures anticipate the sequence determination of purified etc. infectious particles of instant claim 1. Reyes et al. discloses sequence comparison with known sequences inn column 3, lines 4-16, which anticipates the database of known sequence comparisons of instant claims 3 and 13 including plural new viral sequences as required in instant claims 4 and 6. It is noted that viral nucleic acids are extracted and analyzed without culturing in the bridging paragraph between columns 2 and 3 of Reyes et al. as also required in instant claim 7.

CLAIM OBJECTION

Claim 59 is objected to because it includes dependence from non-elected inventions claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 31, 2003

ARDIN H. MARSCHEL